



MAR 26 2009

Jeffrey P. Kushan
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Washington, DC 20005

In Re: Patent Term Extension
Application for
U.S. Patent No. 6,884,879

NOTICE OF FINAL DETERMINATION
AND
REQUIREMENT FOR ELECTION

A determination has been made that U.S. Patent No. 6,884,879, claims of which cover a method of making LUCENTIS® (ranibizumab), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 307 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period.

Applicant also has applied for patent term extension of U.S. Patent No. 6,407,213 and U.S. Patent No. 7,060,269 based on the regulatory review period for the human biologic drug product LUCENTIS® (ranibizumab).

When patent term extension applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance, unless applicant elects a different patent. In the absence of an election by applicant within ONE MONTH of the date of this notice, and in accordance with 37 CFR 1.785(b), the applications for patent term extension of U.S. Patent No. 6,884,879 and U.S. Patent No. 7,060,269 will be denied. Accordingly, the application for patent term extension of the patent having the earlier date of issuance will be granted, i.e., a certificate of extension will be issued to U.S. Patent No 6,407,213 for a period of 378 days.

In the absence of a request for reconsideration, and if U.S. Patent No. 6,884,879 is elected, the Director will issue to the applicant a certificate of extension, under seal, for a period of 307 days in U.S. Patent No. 6,884,879.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of May 29, 2008 (73 Fed. Reg. 30949). Under 35 U.S.C. § 156(c):

Period of Extension	=	½ (Testing Phase) + Approval Phase
	=	½ (2,247 days - 1,999 days) + 183 days
	=	307 days (2.3 years)

Since the regulatory review period began November 6, 1999, before the patent issued (April 26, 2005), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From November 6, 1999, to and including, April 26, 2005, is 1,999 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA's determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

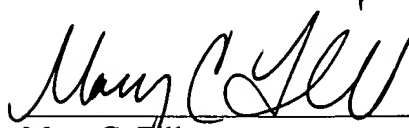
U.S. Patent No.:	6,884,879
Granted:	April 26, 2005
Original Expiration Date ¹ :	August 6, 2017
Applicant:	Manuel Baca et al.
Owner of Record:	Genentech, Inc.
Title:	Anti-VEGF Antibodies
Product Trade Name:	LUCENTIS® (ranibizumab)
Term Extended:	307 days
Expiration Date of Extension:	June 9, 2018

Any correspondence with respect to this matter should be addressed as follows:

By mail:	Mail Stop Hatch-Waxman PTE	By FAX:	(571) 273-7755
	Commissioner for Patents		
	P.O. Box 1450		
	Alexandria, VA 22313-1450.		

¹Subject to the provisions of 35 U.S.C. § 41(b).

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

A handwritten signature in black ink, appearing to read "Mary C. Till", is written over a horizontal line.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: LUCENTIS® (ranibizumab)
Docket No.: FDA-2007-E-0165

Attention: Beverly Friedman